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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,639	10/17/2001	Michael J.P. Lawman	MOR-100D2	8705

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
981,639	LAWMAN et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ R sponsive to communication(s) filed on 7/7/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Dispositi n f Claims

☑ Claim(s) 1-13 is/are pending in the application.

Of the above claim(s) 6-13 is/are withdrawn from consid ration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or lection requirement.

Applicati n Papers

☐ See th attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ Th proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ Th oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ rec ived.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not rec ived: _____.

Attachment(s)

☑ Information Disclosure Stat m nt(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of R ference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Pat nt Drawing Review, PTO-948

☐ Oth r _____

Office Acti n Summary

Claims 1-13 are pending.

Applicant's election without traverse of Group I (claims 1-5) in Paper No. filed 7/7/03 is acknowledged.

The disclosure is objected to because of the following informalities: at page 1, line 7 applicant must update the status of application 09/437,949.

Appropriate correction is required.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing by reciting "a conductive polymer matrix" in the preamble, while merely reciting "a molecule having binding specificity" after "comprising." It is not clear what component forms the "polymer matrix". "It is suggested that applicant recite in accord with teachings at page 7, line 7 – page 8, line 3.

In claim 5 "avidin – related molecules" is unclear, because it is not clear what common property (or properties) is shared by avidin and its "related molecules."

Prior to examination over the prior art, the effective filing date of each claim must be established.

Provisional application 60/030,725 only shows conductive polymers with, antibodies, antigen binding fragments thereof, monoclonal antibodies and anti

CD 34 specific antibodies. Therefore instant claims 2-4 have benefit of the filing date of the '725 application of 11/8/96.

The provisional application shows no other specific binding members. Thus instant claims 1 and 5 only have benefit of the filing date of application 08/965,949 of 11/7/97.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Englebienne et al. (ref. AO).

Englebienne et al. show conductive polymers conjugated to an antigen such as h-CRP. This has "binding specificity" for an antibody to h-CRP. All limitations of claim 1 are thus shown.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Alva et al. (ref. AQ).

Alva et al. teach conductive polymers containing immobilized enzymes such as horseradish peroxidase, alkaline phosphatase and glucose oxidase. Since any enzyme has "binding specificity" for its substrate, claim 1 is anticipated.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (ref. AT; or US 5,843,741).

Wong et al. (AT) teach polypyrrole conductive polymers coated with filbronectin (FN). Since FN has "binding specificity for cell surface integrin receptors (page 3202, col. 2), all aspects of claim 1 are shown.

The '741 patent of Wong et al. teach essentially the same as the journal reference, except for the disclosure of numerous members, beside fibronectin, which have a binding specificity for a target ligand. See col. 9, lines 45+.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribi et al. (5,491,097).

Ribi et al. teach assay devices that include a layer of an electrically conducting surfactant polymer. A specific binding member is bound to this layer. Thus claim 1 is anticipated.

Regarding claim 5, Ribi et al. disclose such a device having avidin bound to the polymer, which has been devitalized with biotin. They also disclose incorporation of Protein A in such devices. See col. 7, lines 23-57.

Regarding claims 2-3; note Ribi et al. teach binding of antibodies or their fragments, including monoclonal antibodies, to the surfactant polymer via a biotin-strept/avidin linkage. See col. 7, lines 41-57 and col. 8, lines 6-28.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribi. (5,156,810).

Ribi '810 teaches essentially the same assay devices as Ribi et al. '097. These include a layer of an electrically conducting surfactant polymer. A specific binding member is bound to this layer.

Ribi teaches the specific binding member can be an antibody (including monoclonals); see col. 9, lines 12-33; col. 11, lines 3-9 and 26-40. Ribi also teaches use of avidin/streptavidin as the specific binding member; see col. 9, lines 3-11; col. 11, lines 10-26. Thus claims 1-3 and 5 are anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Garnier (WO 95/29199 or US 6,096,825).

The Examiner will make reference to the US document.

Garnier teaches conductive polymers conjugated to a "first biological molecule" or "anti-ligand." Such conjugated polymers are used to detect a second biological molecule or ligand; for example the anti-ligand can be an antibody for detecting a target peptide or hapten. See col. 3, lines 35-65. Thus claims 1-2 are anticipated.

Regarding claim 3, Garnier teaches monoclonal antibodies at col. 5, lines 4-9.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (4,839,017).

Taniguchi et al. teach electrically conducting polymer films to which a specifically binding antigen or antibody can be coupled –e.g. see col. 3, line 24 – col. 4, line 5. Thus instant claims 1-2 are anticipated.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (WO 89/03876).

Schnieder teaches electrically conducting polymer films or gels for use in cell culturing. These polymers can be linked to antibodies directed to a cellular antigen(s) of the cells to be cultured. See page 5, lines 19+ and claims 11 and 19. Thus all features of instant claims 1-2 are shown.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (WO 96/04340).

Wallace et al. teach electrically conducting polymers which incorporate a biological macromolecule, which can be released therefrom –e.g. see pages 2-3. The incorporated macromolecule—can be an enzyme, hormone, growth factor, cytokine, or cell membrane receptor or adhesion molecule. See page 3, last full paragraph and page 22, lines 2-5. Each such macromolecule has a corresponding substrate, receptor, or ligand to which it specifically binds. Thus all features of instant claim 1 are shown.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Katoot et al. (6,184,030).

Katoot et al. disclose electrically conducting polymer films. These can be formed so as to incorporate a molecule having "binding specificity", such as an antibody –e.g. see col. 11, lines 25-63. Thus instant clams 1-2 are anticipated. Regarding clams 3-4, Katoot et al. show preparation of such membranes containing monoclonal anti-CD 34 antibodies in Examples I, III, V and XVII-XX.

Regarding the 102 (e) date of Katoot et al. which applicant must overcome, it is to be noted that 08/599,888, filed on 2/12/96 has Examples I, III and V. Provisional application 60/004,757, filed 10/2/95, also has these Examples. Thus the effective 102(e) date is 10/2/95.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Riviello et al. (5,403,451).

Riviello et al. show electrodes coated with a conductive polymer and a biological molecule, such as an antigen or antibody (including monoclonal antibodies) –e.g. see col. 6, lines 3-13 and col. 7, line 50 – col. 8, line 3. This is consistent with claims 1-3.

Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Malmros et al. (4,916,075).

Malmros et al. show test devices having a coating of an oxyacetylene blend film, which serves as a conductive polymer. They show various test devices in which this film is coated with biotinylated enzyme (Examples V-VI), antibody conjugated enzyme (Examples VII-IX), and avidin conjugated enzyme

(Example VIII). Such coated conductive polymers are consistent with instant claims 1-2 and 5.

Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by McNeil et al. (GB 2,276,724).

McNeil et al. teach electrode-based immunoassays. The electrode may be of conductive polymer (abstract) claims 7 and 8). A member of a specific binding pair is immobilized to this electrode (page 3). This member can be an antibody attached directly thereto, or an antibody attached by an avidin/biotin bridge thereto (page 3). These teachings are consistent with instant claims 1-2 and 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

D. A. Saunders:jmr

November 24, 2003